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IN THE

Supreme Court of the United States

OCTOBER TERM, 1998

UNITED STATES SURGICAL CORPORATION,
Petitioner,

v.

APPLIED MEDICAL RESOURCES CORPORATION,
Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

35 U.S.C. § 112 ¶ 1 provides that a patent specification "shall set forth the best mode contemplated by the inventor of carrying out his *invention*."

The question presented is:

Whether Congress requires an inventor to disclose "the best mode" contemplated by him or her to operate the invention as measured by the combination of *all* elements in a patent claim—as opposed to "the best mode" necessary to operate only core elements in the claim, to which the inventor states the invention is "directed"?

LIST OF PARTIES

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of this Petition for Writ of Certiorari.

LIST PURSUANT TO RULE 29.1

Petitioner United States Surgical Corporation is a wholly owned subsidiary of Tyco International Ltd., a publicly traded company. There are no subsidiaries or affiliates of United States Surgical Corporation that have issued shares to the public.

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35 U.S.C. § 112 ..... *passim*

MISCELLANEOUS

3 Donald S. Chisum, *Chisum On Patents* § 7.05 (1998) 9

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PETITION FOR A WRIT OF CERTIORARI

Petitioner United States Surgical Corporation respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Federal Circuit in the above-captioned case.

OPINION BELOW

The opinion of the Court of Appeals is reported at 147 F.3d 1374, and is reproduced at App. ("A.") 1a. The Court of Appeals' order denying rehearing is unreported and is reproduced at A. 23a.[1]

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[1] The District Court issued two published opinions in connection with its disposition of this case. *Applied Med. Resources Corp. v. United States Surgical Corp.*, 967 F. Supp. 861 (E.D. Va. 1997) and 967 F. Supp. 867 (E.D. Va. 1997). The issues addressed in

JURISDICTION

The judgment of the Court of Appeals was entered on June 30, 1998. Petitioner filed a timely petition for rehearing (including a suggestion for rehearing in banc) that was denied on August 21, 1998. A. 23a. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTE INVOLVED

Title 35 U.S.C. § 112, ¶¶ 1 & 2 provide in full (emphasis added):

> *The specification* shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it pertains, or with which it is most nearly connected, to make and use the same, and *shall set forth the best mode contemplated by the inventor of carrying out his invention.*
>
> *The specification shall conclude with* one or more *claims* particularly pointing out and distinctly *claiming the subject matter which the applicant regards as his invention.*

STATEMENT

Petitioner makes a line of medical instruments for minimally invasive surgery. Minimally invasive surgery is performed through small openings in the body created by medical instruments known as trocars. The body cavity is filled with an inert gas under pressure to create an operative space, and a camera is inserted through a trocar to transmit an image of the operative field to a television monitor in the operating room. The surgeon, with an eye on the monitor, operates on internal organs using specially designed instruments that, like the camera, are in-

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these opinions are not relevant to the "best mode" issue presented by this petition. These opinions have been lodged with the Clerk of this Court.

serted through trocars. The trocars and endoscopic instruments passing through them must have seals to inhibit leakage of the inert gas.

A. The District Court Proceedings

Respondent sued petitioner in the United States District Court for the Eastern District of Virginia for patent infringement. 28 U.S.C. § 1338 ("Patents"). Respondent asserted six combination claims [2] in three patents on trocar seal assemblies for safely passing sharp surgical instruments through trocar seals. *Each* asserted claim claimed, in combination, a trocar seal along with a specific structure designed to protect the seal. The patent specifications for all three patents also identified a substance called C-flex® as the preferred material for the seals. However, the inventors in their specifications made no mention of Parylene-C, their preferred coating for the C-flex®. Indeed, the seals did not work without being coated with Parylene-C; it was necessary to carry out the inventions.

Petitioner defended that the patents had not been infringed, and further that the patents were invalid under 35 U.S.C. § 112, ¶ 1 because the specifications failed to disclose the "best mode" contemplated by the inventors for carrying out the inventions—treating and coating of the preferred C-flex® seals with Parylene-C. Denying petitioner's motion for summary judgment, the District Court ruled that there was a factual issue whether the inventors had in fact regarded Parylene-C as the best mode. A. 18a.[3]

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[2] A "combination" claim consists of two or more elements. 35 U.S.C. § 112, ¶ 6.

[3] Respondent argued that for a best mode violation to occur, Parylene-C would have to be shown to have been preferred by *all* inventors. See A. 22a. After the District Court's ruling in this case, the Federal Circuit clarified, to the contrary, that "[b]est mode issues can arise if *any* inventor fails to disclose the best mode known to him or her." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351

At trial, respondent's inventors acknowledged that C-flex® was a soft and sticky seal material that clings to surgical tools, exerts unacceptable friction on them as they pass through an opening in the material, and is susceptible to tears. For that reason, they conceded, C-flex® is not suitable for trocar seals unless it is suitably treated and coated. A. 40a.

It was also conceded that one of respondent's inventors, Donald L. Gadberry, was assigned to search for a satisfactory coating for the C-flex® seal. After a period of experimentation, he identified Parylene-C and a method for applying it, recording his discovery in his laboratory notebook: "This is IT!" and "In other words—it looks great!" A. 23a, 44a-45a. One month later, respondent filed the first of the three patent applications. A. 25a. As another of respondent's inventors testified, Gadberry "was in love with Parylene-C," which became "the Holy Grail." A. 48a.

The engineer in charge of respondent's trocar seal project was its research and development manager, inventor Mark A. Ritchart. As he testified:

> Q. At the time the ['737] patent application was filed in July of 1991, did you have a preferred coating?
>
> A. Yes.
>
> Q. And what was that?
>
> A. That was the Parylene.
>
> Q. And why was that?
>
> A. It was the best coating material that we could come up with.
>
> Q. Now, both the '336 and '553 patents include a seal, do they not?
>
> A. Yes.

---

n.5 (Fed. Cir. 1998) (emphasis added). The District Court noted that Parylene-C was not an obvious coating. A. 16a. (The best mode must be disclosed even if obvious. *Dana Corp. v. IPC Ltd. Partnership*, 860 F.2d 415, 419 (Fed. Cir. 1988).).

Q. And the '737?
A. Yes.
Q. With respect to all three of your inventions, could these inventions work without Parylene-C?

* * * *

A. No, they didn't.
Q. Why didn't they work?
A. The seal was way too sticky and susceptible without some sort of coating on it.

* * * *

Q. Was there another coating you [p]referred over Parylene-C?
A. No.

A. 40a-41a. Ritchart also testified that through oversight (A. 42a) he forgot to inform respondent's patent counsel about Parylene-C, A. 43a, so that C-flex® was identified as the preferred material in the specification and also specifically claimed in the '737 patent,[4] the necessary Parylene-C coating was not disclosed in any of the three patent applications.[5]

After a jury found the patents valid and infringed, petitioner renewed its motion for judgment as a matter of law, on the ground that the undisputed evidence established that Parylene-C had been the inventors' best mode of carrying out the invention, and that it had not been disclosed. Respondent argued that the "inventions" for purpose of best mode analysis consisted not of the totality of the elements in the asserted claims, but only of those elements in the claims that described the specific structures that worked without application of Parylene-C:

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[4] '737 claim 10 reads as follows: "The trocar as recited in claim 9, wherein said low durometer polymer is C-flex®."

[5] It has long been settled that 35 U.S.C. § 112 is violated, and the patent consequently invalid, if disclosure of the best mode is not made, whether or not there was intent to conceal it. *Dana Corp.*, 860 F.2d at 418.

the pre-dilator, the protector, and the floater. Respondent based its argument on testimony from the inventors such as this testimony from inventor Ritchart:

> Q. Okay. And the purpose of the '336 patent was to have a physical protection for the septum seal, correct?
>
> A. Yes.
>
> Q. And that was what was, as you understood it, the coverage of the '336, *core* of the '336?
>
> A. The physical protection mechanism, yes.
>
> Q. And Parylene-C was not part of that physical protective mechanism in the '336, correct?
>
> A. [I]n the '336, it was not.

A. 41a (emphasis added).

Defining the "inventions" as consisting of only those specific structures (the pre-dilator, the protector, and the floater) that did not depend on Parylene-C for their operation, respondent argued that Parylene-C was not necessary to carrying out the inventions, and therefore was not required to be disclosed as the best mode for the invention under § 112.

Petitioner responded that each asserted claim indisputably contained a trocar seal element in addition to those elements claiming the pre-dilator, the protector, and the floater, and it was undisputed that Parylene-C was preferred, indeed necessary, for the seals to work. Petitioner argued that, as a matter of law, the "invention" under § 112 is defined by *all* elements combined in a claim and not just a portion of a claim.

By way of example, claim 1 of the '737 patent reads as follows:

> 1. A trocar assembly having a channel defined along an elongate axis, the trocar assembly being adapted to receive an instrument having a particular cross-sectional dimension, said trocar assembly comprising:

> [a] an elastomeric septum disposed in said channel and including portions defining an orifice having in a relaxed state a first cross-sectional area and in an expanded state a second cross-sectional area; and
>
> [b] means responsive to the particular dimension of the instrument for expanding said orifice to the second cross-sectional area.

A. 27a. Claim element [a] is the trocar seal, the structure corresponding to claim element [b] is the seal pre-dilator.[6] Petitioner contended that Congress intended for "best mode" to apply to [a] as well as [b]. Respondent argued that its inventors' disclosure obligation was limited to [b].

The District Court denied petitioner's motion and entered judgment against petitioner for damages of $20,470,962.81. The Court also enjoined petitioner from continuing to market infringing surgical products, the pre-injunction sales value of which was approximately $210 million.

B. The Court of Appeals' Holding

The Court of Appeals for the Federal Circuit affirmed. The Court of Appeals acknowledged that "Surgical correctly notes that each asserted claim contains a trocar seal limitation."[7] A. 4a. It acknowledged also that the undisclosed Parylene-C coating was not only preferred but necessary for the seals to work. A. 5a. In the dispositive part of its opinion, interpreting the meaning of the word "invention" in 35 U.S.C. § 112, ¶ 1, the Federal Circuit held:

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[6] Claim element [b] is a "means plus function" claim element. 35 U.S.C. § 112, ¶ 6. The corresponding structure is the pre-dilator. The District Court so defined this element for the jury.

[7] The term "limitation" is used interchangeably with "element" in the patent law, and the Court of Appeals did so in its opinion. *Cf.* also *e.g.*, 35 U.S.C. § 112 ¶ 4 with *id.* ¶ 6.

> "while a lubricant like Parylene-C is necessary to the operation of the trocar and the seal, it plays no role in the functioning of the pre-seal dilator, the seal protector, and the floating seal, which, Messrs. Hart and Feinberg [8] explained,[9] are the inventions to which the '737, '366 and '533 patents are directed respectively."

A. 5a. The Court of Appeals described § 112's "best mode" provision as requiring

> "that an applicant is obliged to disclose nonclaimed elements necessary to the operation or carrying out of *the invention to which the patent is directed*. . . . However, where the invention relates only to a part of, or only one aspect of, a device, *an applicant is not required to disclose a nonclaimed element necessary to* the operation of *the overall device, but not necessary to* the operation of *the invention to which the patent is directed*."

A. 4a. (emphasis added). The Court of Appeals concluded, based on the testimony it cited, that "[i]t is evident from the patents that *they are directed to* the inventions of a seal pre-dilator, a seal protector, and a seal floater." A. 5a (emphasis supplied). On that basis, it held, there was support for a jury verdict of no best mode violation. A. 5a. The Court of Appeals acknowledged that a similar case had reached the opposite result;[10] the court explained that in the earlier decision the undisclosed coating "was necessary to the satisfactory performance of the invention to which the patent was directed, the valve stem seal." A. 5a. A petition for re-

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[8] Hart was an inventor; Feinberg was respondent's expert witness. Hart's testimony is at A. 48a-49a; Feinberg's at A. 50a-51a.

[9] The Court of Appeals also relied on the cross-examination of Ritchart (A. 5a), quoted in the text at p. 6, *supra*.

[10] *Dana Corp. v. IPC Ltd. Partnership*, 860 F.2d 415 (Fed. Cir. 1988).

hearing with suggestion for rehearing in banc was denied. A. 23a.

REASONS FOR GRANTING THE WRIT

I. THE SCOPE OF THE INVENTOR'S STATUTORY BEST MODE DISCLOSUURE REQUIREMENT IS AN ISSUE OF EXCEPTIONAL PUBLIC IMPORTANCE

The country's principal patent court has redefined the word "invention" in 35 U.S.C. § 112, ¶ 1 to mean, not the entire combination as stated in a patent claim, but only those portions of the claim a jury or a court later decides the invention was "directed to." There is no precedent supporting this decision. It flies in the face of the statutory text and years of decisions that understood "invention" to mean the entire claim, not just some uncertain portion of it.

If the Court of Appeals' new interpretation stands, henceforth to establish a "best mode" violation under § 112, the challenger will have to establish not only that the undisclosed mode was preferred and necessary to the operation of a claimed element—but also that the element was one which the invention was "directed to." That determination, the Court of Appeals also holds can be made, presumably by a jury (as in this case), based on after-the-fact testimony by inventors or their expert as to their subjective opinions about claim scope.

A whole new issue for patent litigation has been created. This novel holding not only carries enormous monetary consequences for the litigants, but also unsettles the patent law in a way that will produce administrative difficulties in the district courts, and will eliminate, in an unpredictable number of cases, the duty to comply with a basic disclosure that Congress for more than two centuries has mandated. *See* 3 Donald S. Chisum, *Chisum On Patents* § 7.05, at 192-93 (1988).

The issue of whether the statutory best mode disclosure requirements has been satisfied arises frequently in patent litigation. This statutory requirement is at the heart of the patent law. As this Court noted in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989) (O'Connor, J.,), a patent applicant must be "willing to reveal to the public the substance of his discovery and 'the best mode . . . of carrying out his invention,'" as part of "a carefully crafted bargain . . . in return for the exclusive right to practice the invention for a period of years." *Id.* at 150-51 (first ellipsis in original) (quoting 35 U.S.C. § 112, ¶ 1); *see also Pfaff* v. *Wells Electronics, Inc.*, No. 97-1130, 1998 WL 777044, at *5 (U.S. Nov. 10, 1998) (discussion of "balance" in patent system). The public is entitled to dedication of the invention, including the best mode of practicing it, upon expiration of the patent.

This case presents the basic issue of what is meant by "invention" in best mode analysis. It is not defined in 35 U.S.C. § 112, ¶ 1.

The Court of Appeals' decision allows an inventor to conceal the best mode—even though it is necessary to carry out a claimed element— so long as it is not relevant to the claimed element that the inventor contemplates as his or her invention. As a result, the decision encourages inventors (and their corporate employers) to keep secret any preferred mode necessary to operate claim elements other than those to which the invention was "directed." That is plainly contrary to both the language and basic policy of the statutory "best mode" requirement. No public purpose is served in granting a long-term monopoly to a patentee, yet allowing the patentee (or the assignee corporation) to retain as a trade secret a preferred mode necessary to the operation of *any* element of an invention as stated in a patent claim.

This case illustrates the great harm to the public from the Court of Appeals' decision. Respondent's inventions have no commercial value without disclosure of Parylene-C

because the C-flex® seals described in the patents will not work without this treatment. The Court of Appeals decision allows a patent monopoly to be obtained without disclosing anything of practical value.

So long as Court of Appeals' decision stands, the public is being denied its side of the patent bargain. The panel decision, written by the Chief Judge, represents the considered position of the entire Court.[11] Because the Court of Appeals for the Federal Circuit has appellate jurisdiction over all patent cases, its decision in this case will remain the controlling precedent unless and until changed by this Court. The issue of whether "invention" in 35 U.S.C. § 112, ¶ 1 includes *all* elements of a combination claim—or, as the Court of Appeals holds, only those elements within the combination to which the claim "is directed," is an issue of pressing and substantial public importance meriting review by this Court.

II. THE COURT OF APPEALS' REDEFINITION OF "INVENTION" IS SQUARELY IN CONFLICT WITH THIS COURT'S FUNDAMENTAL PATENT DECISIONS, INCLUDING *MARKMAN*, *ARO I*, AND THE *MERCOID CASES*

Congress did not define "invention" in 35 U.S.C. § 112, ¶ 1. It simply stated that the specification "shall set forth the best mode contemplated by the inventor of carrying out his invention." But Congress in the next paragraph, 35 U.S.C. § 112, ¶ 2, stated that an inventor following the specification "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

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[11] The Court of Appeals for the Federal Circuit circulates precedential decisions to all judges of the Court before they are filed; the Court as a whole thereby "impliedly" clears all precedential decisions before they are released. Fed. Cir. Clerk's Office, Memorandum, *Questions and Answers About Petitions for Rehearing and Suggestions for Rehearing in Banc in the United States Court of Appeals for the Federal Circuit* (undated but current).

Given that Congress in ¶ 2 equated "invention" with "claim"—not just that part of a claim to which an inventor later testifies his or her claim is "directed"—it is plain that Congress did not have and could not have had any different meaning of "invention" in mind in ¶ 1. *Caminetti v. United States*, 242 U.S. 470, 485 (1917).

In *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), this Court after reciting 35 U.S.C. § 112, ¶ 2, explained: "The claim defines the scope of a patent grant." 517 U.S. at 373 (quotation & brackets omitted). Thus, this Court, following the clear words of Congress in 35 U.S.C. § 112, ¶ 2, equated "invention" with "claim." 517 U.S. at 373. The Court of Appeals' decision is directly in conflict with *Markman* because "invention" under the Court of Appeals' new best mode holding is not the claim, including all elements of it—but instead is restricted to the element or elements to which the claim is said to be "directed." A. 4a-5a. The Court expressly relies on inventor testimony identifying the "core" of his invention as guidance for what the invention is "directed to." A. 5a (citing cross-examination of Ritchart).

The Court of Appeals' decision is a throwback to the "heart" of the invention approach to claim scope which was expressly rejected by this Court years ago, most recently in *Aro Manufacturing Co. v. Convertible Top Replacement Co. ("Aro I")*, 365 U.S. 336 (1961). In *Aro I*, the patent assignee complained that a repairer infringed by replacing a particularly shaped fabric part that the assignee argued was at "the very 'heart' of the invention—which brought the combination up to the inventive level." *Id.* at 344. This Court differed: "We cannot agree. For if anything is settled in the patent law, it is that the combination patent covers only the totality of the elements in the claim and that no element, separately viewed, is within the grant." *Id.* at 344. This Court continued: "Yet this Court has made it clear in the two Mercoid cases that there is no legally recognizable or protected *'essential'*

element, *'gist'* or *'heart'* of the invention in a combination patent." *Id.* at 345 (emphasis added). Thus, in the typical patent consisting of one or more combination claims, like all claims in this case, the invention consists of the entire combination and not just some element later selected on an entirely subjective and unpredictable basis.

The Court of Appeals' decision, in holding that there is no best mode violation unless the undisclosed mode goes to that part of the claim to which the invention (is said to be) directed, ignores that a claim consists of the totality of elements as set forth therein, not just that element deemed at the "essence" or "heart" or "gist"—or "*core*" [12]—of the invention. *Aro I*, 365 U.S. at 344-45, 360 (emphasis added). The Court of Appeals' decision is in direct conflict with *Aro I*, which in turn is a reiteration of the fundamental principle as stated in the *Mercoid* cases, *Mercoid Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661, 667 (1944) and *Mercoid Corp. v. Minneapolis-Honeywell Regulator Co.*, 320 U.S. 680, 684 (1944), that an invention in a combination patent consists of *all* elements as stated in a claim, no more and no less.

The Court of Appeals, in response to petitioner's argument, acknowledged that each of the six asserted claims contains a trocar seal element. A. 4a. The seal element is therefore a component of each claimed combination.[13] That being so, there is no escape under this Court's decisions in *Aro I* and the *Mercoid* cases from the legal conclusion that failure to disclose Parylene-C is a best

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[12] "A fundamental error . . . is the notion that in a case of this kind a court is obliged to search for the alleged 'heart' or '*core*' of the combination patent." 365 U.S. at 360 (emphasis added). "Core" is the very word used by counsel for respondent in his questioning of inventor Ritchart. See Statement at p. 6, *supra*.

[13] The claims use "seal," "septum," and "valve" interchangeably. *E.g.*, "the valve being formed of an elastomeric material." A. 32a. In truth, the seal permeates all elements of each claim.

mode violation, as it is necessary to the operation of the trocar seal element (as the Court of Appeals concedes, A. 4a) of each asserted claim.

The Court should grant certiorari because the Court of Appeals' decision rewrites a heretofore plain statute and is not faithful to *Markman*, *Aro I*, and the *Mercoid* cases —all cases fundamental to this Court's patent jurisprudence.

III. THE COURT OF APPEALS' DECISION IS IMPOSSIBLE TO ADMINISTER AT EITHER THE TRIAL OR APPELLATE LEVEL

The Court of Appeals' decision will create confusion and difficult burdens for the federal trial courts. The relevancy test in best mode analysis should be a bright-line test, easy to administer. The bright-line rule in best mode cases has been that the claim, including all elements of it, provides the relevancy standard against which an inventor's compliance with his or her best mode obligation must be measured.

The decision below not only lacks textual support; it is impossible to administer. It creates a factual issue (Does the undisclosed best mode relate to the core of the claim?) when there should be none (the scope of a claim is an issue of law). It imposes an immediate and intolerable burden on federal trial courts confronted with best mode issues. They deserve the benefit of a bright-line test, as proposed herein, to ensure objective and efficient resolution of best mode disputes.

If, as the courts have held until now, the invention is the claim in its entirety, including all claim elements, then there is an objective basis for determining "best mode" relevancy. The undisclosed preferred mode either is relevant to the claim, including any element of it, or it is not. However, if now "best mode" relevancy is to be limited to the "core" of the invention, then the courts—and juries—must resolve what is at the "core" of the claim and what is not at the "core" of the claim. This is an impossible task.

For example, in this case the jury accepted the position as set forth in the cross-examination of inventor Ritchart that the best mode violation did not go to the "core" of the claims. A. 22a. But the purpose of the *seal* pre-dilator, the *seal* protector, and the *seal* floater was to facilitate the work of the trocar *seal* which, surely, is at the "core" of the inventions. An effective trocar seal was respondent's inventors concern and goal.[14] Courts (and juries) are in no position to identify the "core" of a claim (what an invention is "directed to") because "the core" is too subjective, too fuzzy, too difficult (and time consuming) to analyze, and much too prone to hindsight revisionism.[15]

The position urged by petitioner in the Court of Appeals and in this Court was squarely supported, until now, in the best mode precedents of the Court of Appeals. They stated that "best mode" relates to the "claimed invention." There is no suggestion in prior Court of Appeals' cases that this obligation is restricted to only some unarticulated

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[14] The Court of Appeals writes: "It is evident from the patents that they are directed to the inventions of a seal pre-dilator, a seal protector, and a seal floater." A. 5a. Indeed, the patents are titled: "Lever Actuated Seal System" ('737 patent, A. 25a), "Seal Protection Mechanism ('336 patent, A. 29a), and "Trocar With Floating Septum Seal" ('553 patent, A. 34a). But, what may superficially seem "evident" is in fact highly contentious: under an amorphous "directed to" standard petitioner would still urge that respondent's inventions were "directed to" a working seal—which explains why the trocar seal element is an element of all claims, why the word "seal" is in the title of each patent, and also why the inventors specifically *claimed* C-flex®. *See* note 4, *supra*. Indeed, the fact that the inventors claimed C-flex® as their preferred seal material underscores the relevance of their preferred coating and the gravity of their best mode omission.

[15] Wholly apart from hindsight revisionism, inventors often have a misperception of the actual scope of their claims for the simple reason that they typically delegate claims' drafting to skilled patent attorneys. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 389 (1996) ("the claims of patents have become highly technical in many respects as the result of special doctrines relating to the proper form and scope of claims" (quotation omitted)).

portion of a claimed invention. *E.g., United States Gypsum Co. v. National Gypsum Co.*, 74 F.3d 1209, 1212 (Fed. Cir. 1996) (best mode inquiry relates to "claimed invention"); *Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1531 (Fed. Cir. 1991) (best mode inquiry "measured by the claims"); *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927-28 (Fed. Cir. 1990) (best mode relates to "claimed invention"). Indeed, there are "best mode" precedents that impose a disclosure obligation broader than the claim-based, best mode relevancy test urged by petitioner. *E.g., Flick-Reedy Corp. v. Hydro-Line Mfg. Co.*, 351 F.2d 546, 550 (7th Cir. 1965) (inventor disclosed special tool in specification but did not describe it or claim it; still, he committed a best mode violation); *see generally Robotic Vision Sys. Inc. v. View Eng'g Inc.*, 112 F.3d 1163, 1166 (Fed. Cir. 1997) ("[C]arrying out the invention usually involves more than what is expressly claimed.").

The decision below moves "best mode" law outside the mainstream of patent law, holding that in § 112, ¶ 1 alone 'invention" is to mean only that part of the claim to which the invention is "directed," not the invention as defined by the entire combination claim. Most recently, in *Pfaff*, this Court noted that the on-sale bar in 35 U.S.C. § 102(b) applied because Pfaff, more than one year before he applied for his patent, provided Texas Instruments with detailed drawings of sockets that "contained all elements of the invention claimed in the '377 patent." 1998 WL 777044, at *7. Just as an "all elements" rule is the basis for applying the statutory on-sale bar requirement under § 102(b), so also it should be the basis for applying the statutory best mode requirement under § 112, ¶ 1. Congress used "the invention" in both sections; there is no textual support whatsoever for legally concluding that "the invention" in §102 means "all elements" but "the invention" in § 112, ¶ 1 means less than all elements. *See also Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565 (Fed.

Cir. 1991) ("We find the district court's concern with 'what the invention is' misplaced . . . . 'The invention' is defined by the claims on appeal."). The Federal Circuit's decision below introduces uncertainty and confusion, and avenues for litigation (especially jury litigation, as in this case), heretofore unimagined.

CONCLUSION

For the reasons stated, certiorari should be granted.

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

97-1526

APPLIED MEDICAL RESOURCES CORPORATION,
Plaintiff/Appellee,

v.

UNITED STATES SURGICAL CORPORATION,
Defendant-Appellant.

DECIDED: June 30, 1998

Before MAYER, *Chief Judge,* PLAGER and SCHALL, *Circuit Judges.*

MAYER, *Chief Judge.*

United States Surgical Corporation appeals from the judgment of the United States District Court for the Eastern District of Virginia, Civ. Action No. 96-CV-1217 (June 10, 1997). We affirm.

Background

Applied Medical Resources Corporation (Applied Medical) owns United States Patents Nos. 5,209,737, 5,308,336, and 5,385,553, all relating to advances in trocar seal technology.[1] Applied Medical sued United

[1] The '553 patent is a continuation-in-part of the application that matured into the '336 patent, which is a continuation-in-part of the application that matured into the '737 patent.

States Surgical Corporation (Surgical) for, *inter alia*, infringing claims 1 and 32 of the '737 patent, claims 4 and 23 of the '336 patent, and claim 18 of the '553 patent with its Versaport trocar, and for infringing claim 4 of the '553 patent with the Premium Surgiport Seal Adapter System. Surgical denied infringement and advanced an affirmative defense that the SureSeal floating valve and the EndoPort™ five millimeter trocar anticipated the asserted claims of the '553 patent. It also advanced as an affirmative defense that the inventors of all three patents failed to disclose the best mode of practicing the inventions. Surgical moved for summary judgment on the basis of these defenses. Finding factual disputes, the court denied Surgical's motion on anticipation, but deferred judgment on the alleged violations of the best mode requirement until the close of evidence.

The jury found all three patents infringed and not invalid. The jury also found the infringements to be willful and fixed damages at a single royalty rate of seven percent. The court denied Surgical's renewed motion under Federal Rule of Civil Procedure 50(b) for judgment as a matter of law, permanently enjoined Surgical from making or selling the infringing devices, and enhanced damages to a total in excess of twenty million dollars.

Surgical appeals the trial court's ruling on the affirmative defenses, its decision to exclude from evidence the opinion of an administrative patent judge resolving a patent interference proceeding, and its circumscription of expert testimony relating to the possible range of means-plus-function equivalents.

Discussion

We review a trial court's decision on a motion for judgment as a matter of law following a jury verdict by reapplying its own standard of review. *See, e.g., Dana Corp. v. IPC Ltd. Partnership*, 860 F.2d 415, 417, 8

USPQ2d 1692, 1694 (Fed. Cir. 1988). Therefore, for Surgical to prevail on appeal it must prove that the jury's factual findings were not supported by substantial evidence or that the facts were not sufficient to support the conclusions necessarily drawn by the jury on the way to its verdict, *see, e.g., Unidisco, Inc. v. Schattner*, 824 F.2d 965, 967, 3 USPQ2d 1439, 1441 (Fed. Cir. 1987); *D.M.I., Inc. v. Deere & Co.*, 802 F.2d 421, 425, 231 USPQ 276, 278 (Fed. Cir. 1986); *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1512-13, 220 USPQ 929, 936 (Fed. Cir. 1984), or that the trial court applied the law erroneously, *see, e.g., Dana Corp.*, 860 F.2d at 418, 8 USPQ2d at 1695.

The trial court may grant Surgical's motion for judgment as a matter of law only if, upon the record before the jury, it was convinced that reasonable persons could not reach a verdict for Applied Medical. *See, e.g., Railroad Dynamics*, 727 F.2d at 1513, 220 USPQ at 936. Thus, on appeal we must consider the evidence of record in the light most favorable to Applied Medical, drawing all reasonable inferences in its favor, without disturbing the jury's credibility determinations or substituting our resolutions of conflicting evidence for those of the jury. *See, e.g., Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1546, 220 USPQ 193, 197 (Fed. Cir. 1983).

Best Mode

The first paragraph of section 112 provides in relevant part that the specification "shall set forth the best mode contemplated by the inventor of carrying out his invention.' 35 U.S.C. § 112 ¶ 1 (1994). We have held that this analysis includes two components:

> The first is whether at the time the inventor filed his patent application, he knew of a mode of practicing his claimed invention that he considered to be better than any other. This part of the inquiry is wholly subjective, and resolves whether the inventor must

> disclose any facts in addition to those sufficient for enablement. If the inventor in fact contemplated such a preferred mode, the second part of the analysis compares what he knew with what he disclosed —is the disclosure adequate to enable one skilled in the art to practice the best mode or, in other words, has the inventor "concealed" his preferred mode from the "public"? Assessing the adequacy of the disclosure, as opposed to its necessity, is largely an objective inquiry that depends upon the scope of the claimed invention and the level of skill in the art.

Chemcast Corp. v. ARCO Indus. Corp., 913 F.2d 923, 927-28, 16 USPQ2d 1033, 1036-37 (Fed. Cir. 1990). Because the first component focuses on the applicant's state of mind, a question of fact, we review this aspect of the jury's verdict for substantial evidence. *See, e.g., In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1536, 25 USPQ2d 1241, 1248 (Fed. Cir. 1992); *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1037. In so doing, we observe that an applicant is obliged to disclose nonclaimed elements necessary to the operation or carrying out of the invention to which the patent is directed. *See, e.g., Dana Corp.*, 860 F.2d at 418, 8 USPQ2d at 1695 (fluoride surface treatment "necessary to satisfactory performance of [the] seal"); *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1037. However, where the invention relates only to a part of, or one aspect of, a device, an applicant is not required to disclose a nonclaimed element necessary to the operation of the overall device, but not necessary to the operation of the invention to which the patent is directed.

Surgical correctly notes that each asserted claim contains a trocar seal limitation and that the patents disclose a preference for a soft, stretchy and sticky seal made of low durometer polymer material, such as C-flex®. From these facts, Surgical concludes that the patents are invalid for failing to disclose the use of Parlyene-C—which at

some point became the preferred lubricant for coating the seal—because a coating, such as Parylene-C, is necessary to prevent tearing.[2]

Surgical relies on the testimony of a named inventor, Mark Ritchart and the testimony of a technical expert, Ronald Luther, to prove that the three inventions could not work without Parylene-C. However, Applied Medical challenged this testimony with the testimony of Charles Hart and Barry Feinberg, and the cross-examination of Ritchart, explaining that while a lubricant like Parylene-C is necessary to the operation of the trocar and the seal, it plays no role in the functioning of the pre-seal dilator, the seal protector, and the floating seal, which Messrs. Hart and Feinberg explained, are the inventions to which the '737, '336, and '553 patents are directed, respectively.

It is evident from the patents that they are directed to the inventions of a seal pre-dilator, a seal protector and a seal floater. It is in this respect that we reach a different result than we did in *Dana Corp.*, 860 F.2d 415, 8 USPQ2d 1692, where the fluoride surface treatment was necessary to satisfactory performance of the invention to which the patent was directed, the valve stem seal. Although both Surgical and Applied Medical present arguments about the proper interpretation of the conflicting testimony as to the relevance of Parylene-C, there is substantial evidence to support the jury's presumed finding on the matter. In sum, there is substantial evidence to support the jury's verdict that Surgical failed to prove by clear and convincing evidence that the inventors violated the first component of section 112's best mode disclosure requirement.

Anticipation

"A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publica-

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[2] Parylene-C reduces the friction coefficient of the seal.

tion in this or a foreign country or in public use or on sale in this country, more than a year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b) (1994). We have interpreted this statute as requiring a party seeking to invalidate a patent to prove that the allegedly invalidating patent or publication contains "each and every element of [the] claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 USPQ2d 1766, 1767 (Fed. Cir. 1987); *see also In re Graves*, 69 F.3d 1147, 1151, 36 USPQ2d 1697, 1700 (Fed. Cir. 1995) (whether a reference is anticipatory is a question of fact). A party seeking to prove anticipation must do so with clear and convincing evidence because the patent must be presumed valid. *See, e.g., Verdegall Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987); *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir. 1984). Thus, the legal question on appeal is whether the jury had substantial evidence upon which it could conclude that Surgical failed to prove by clear and convincing evidence that a patent or publication contained each and every element of the '553 patent claims.

Surgical contends that each and every element in the asserted claims of the '553 patent was present in both the EndoPort™ 5 millimeter trocar that was commercially available in the mid-1980s and the SureSeal valve that Applied Medical demonstrated at a medical conference in April 1992. Because the '553 patent was filed on June 15, 1993, the April 1992 demonstration of a trocar containing the SureSeal valve can be invalidating only if the '553 patent is not entitled to a filing date that precedes April 1992. *See, e.g., Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1421, 5 USPQ2d 1194, 1197 (Fed. Cir. 1987) (a continuation-in-part application is entitled to the filing date of an earlier filed application if "the inventor had possession of the later-claimed

invention on the filing date of the earlier application" and disclosed the invention in the earlier filed patent).

To begin with, Surgical misses the import of the district court's review. On appeal, Surgical states: "Surgical must show that there is no substantial evidence that would support a jury determination that Applied's own SureSeal trocar did not anticipate the '553 claims at issue. But, given that this was undisputed, the real issue was whether the '553 patent was entitled to the '737 or '336 priority date . . . ." The allegedly undisputed evidence to which Surgical referred is Luther's testimony comparing defendant's exhibit 273, the SureSeal valve brochure, to the fifth element of the '553 patent's eighteenth claim. This testimony reads in relevant part:

> Q. And directing your attention to the means plus function in the last clause, does that show—or what is it in that drawing that satisfies Element 5 of the means plus function claim?
>
> A. It depicts the levers, seal, and that sort of thing.
>
> Q. The portion of element 5, as the Court has construed it, relates to the possibility of two elements, either a bump or an excess of material, or a ring with levers.
>
> Are either of these structures set forth in the variable diameter seal drawing as shown here?
>
> A. The ring with levers is set forth there.
>
> Q. Is there any excess material shown on that drawing as well?
>
> A. Yes, there is.
>
> Q. And where is that excess material shown relative to the levers?
>
> A. It's just outboard of the—if you take the bottom of the seal and you go up one piece of the diagram and you go outboard, you see the bump there.

The fact that Applied Medical did not contest this point with testimony from one of its own experts no more resolves the factual question in Surgical's favor, *see, e.g., Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092, 44 USPQ2d 1459, 1462 (Fed. Cir. 1997) (affirming district court's finding of infringement despite unrebutted expert testimony to the contrary because "[n]othing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness"), than it satisfies the legal standard requiring judgment as a matter of law. The proper question we must ask, as did the district court, is whether the jury had substantial evidence upon which to conclude that Surgical failed to prove by clear and convincing evidence that the SureSeal trocar discloses each and every element and thus anticipates the '553 patent. The trial court determined that it did.

> Luther did testify that each and every element of the '553 [patent] was disclosed in the Sure-Seal materials, but it is possible, given the trial as it proceeded, that the jury could have concluded that this testimony was not credible.
>
> When he was asked why the SureSeal drawing satisfied Element 5 of the '553 Patent's means plus function claims, he said it depicts levers, seal and that sort of thing.[3]
>
> That's not the kind of overwhelming evidence needed. So, in the Court's view there is and there was some evidence to the contrary, and I the [sic] think that the jury could have concluded that Surgi-

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[3] By contrast, claim 18 of the '553 patent claims: "means disposed circumferentially outwardly of the valve portions for supporting the valve portions within the seal housing, the supporting means being movable relative to the housing to permit the valve portions to float relative to the axis of the cannula."

> cal didn't met [sic] its heavy burden of showing invalidity.

For the same reason delicately articulated by the district court in its oral ruling, we see no reason to hold otherwise. *See, e.g., OrthoKinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570, 1 USPQ2d 1081, 1084 (Fed. Cir. 1986) ("[A] jury or a court may reach a conclusion that a patent remains valid solely on the failure of the patent challenger's evidence to convincingly establish the contrary."). We acknowledge the various reasons found throughout the record for why Luther's testimony may not be credible, but any credibility determination is not ours to remake. In sum, we cannot say that the jury lacked substantial evidence upon which to conclude that Surgical failed to prove by clear and convincing evidence that claims 4 and 18 of the '553 patent were anticipated by Applied Medical's own SureSeal trocar.

As for anticipation by the EndoPort™ 5 millimeter trocar, Surgical's witnesses, Luther and Murphy, testified that the EndoPort™ trocar possessed a bellows structure that permitted off-axis insertion of an instrument through the trocar and permitted the seal to float—both elements being required by claims 4 and 18 of the '553 patent. Luther and Murphy explained that the EndoPort™ trocar had bellows that permitted off-axis insertion of the instrument and floating of the seal, as well as ribs on these bellows, which were designed to prevent the seal from inverting when the instrument was removed. Surgical also had Murphy demonstrate floating movement of the seal and off-axis manipulation using the EndoPort™ trocar and a balloon. Finally, Surgical presented evidence that at one point the manufacturer of the EndoPort™ trocar referred to a portion of its seal as "bellows."

Applied Medical countered this evidence with testimony from Feinberg, who stated that while the EndoPort™ trocar's seal could move, the ribs—incorporated to prevent

inversion of the seal—prevented the bellows from floating and from being manipulated off-axis without creating a "cat's eye" through which insufflation gas would leak. Applied Medical further supported this testimony with portions of Murphy's testimony, and with the fact that Murphys' demonstrative balloon deflated significantly during manipulation intended to simulate off-axis and floating movements.

The fact that the EndoPort™ trocar can be moved, off-axis, did not require the district court to grant Surgical's motion for judgment as a matter of law on its anticipation defense. While the experts may use the same words, such as "floating" and "bellows," to describe both the '553 patent and the EndoPort's seal, it is apparent that they are being used in different ways to connote different intended functions. The EndoPort™ trocar cannot anticipate the '553 patent simply by possessing identically named parts, unless these parts also have the same structure or otherwise satisfy the claim limitation, and were understood to function in the same way by one skilled in the art. *Cf. Intellicall, Inc., v Phonometrics, Inc.*, 952 F.2d 1384, 1388, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992) (An inventor may "be his own lexicographer and . . . give terms uncommon meanings."). It was within the province of the jury to make such findings, and given the testimony and its credibility determinations we cannot say the jury did not have substantial evidence upon which to conclude that Surgical did not prove by clear and convincing evidence that the EndoPort™ trocar anticipated the asserted claims of the '553 patent.

Infringement

We review evidentiary rulings of the district court for abuse of discretion, and interfere with its judgment only if an erroneous ruling prejudiced substantial rights. *See, e.g., Kolmes v. World Fibers Corp.*, 107 F.3d 1534, 1542, 41 U.S.PQ2d 1829 1834 (Fed. Cir. 1997). Surgical

argues that the trial court abused its discretion by excluding the opinion of an administrative patent judge, *Ritchart v. Green,* Interference No. 103,459 (March 21, 1996), resolving an interference proceeding between U.S. Patent Appl'n No. 08/185,102 (Green application) and the '737 patent, and that by excluding this opinion the district court prejudiced Surgical's substantial rights.

The administrative patent judge's order said that while the Green application's "thin and flexible 'fingers' may assist in enlarging the orifice by *distributing* the expansive force and spreading it throughout the membrane material when an instrument contacts the fingers, [the '737 patent's] rigid levers *concentrate* and *focus* the enlarging force in the lateral direction and with a mechanical advantage not obtainable with Green's soft and flexible fingers." Thus, it reasoned: "Given either structure or configuration as prior art, the other would not have been obvious to one with ordinary skill in the art." Surgical argued that the accused Versaport trocar is very similar to the Green patent and thus sought to introduce this opinion as part of the '737 patent's file wrapper used by its technical expert, Luther, to arrive at his opinion that there are more than insubstantial differences between the '737 patent and Surgical's Versaport trocar.

The district court sustained Applied Medical's objection to the introduction of the administrative patent judge's opinion because:

> This is an issue of fact, on whether something is insubstantial. The . . . ALJ's opinion will really preempt that from the jury's determination.
>
> This expert is . . . a technical expert. He can give an opinion as to what is insubstantial, and he would no more be able to rely on that than he would be if some judge in the Southern District of NewYork had said it, or somewhere else.
>
> * * * *

> Nothing I have said prevents you [Surgical] from eliciting from this expert [Luther] that he believes that there is an insubstantial difference, and why—and if those reasons are the same reason that the ALJ gave, there is noting to prevent him from saying that.
>
> * * * *
>
> What I am precluding is him saying, "And by the way, there is a [sic] administrative law judge in the course of this inference who agrees with me."

This narrow exclusion prevented Surgical from augmenting the credibility of its expert's testimony by aligning it with the administrative patent judge's factual finding. Such alignment could conflate factual inquiries—the administrative patent judge's finding and a finding on the substantiality of differences between the '737 patent and the Versaport trocar—in a way that might prejudice or overshadow the latter, more directly relevant finding. By permitting Surgical to present through expert testimony the same arguments it made during the interference, the trial court's decision left the administrative patent judge's factual inquiry to the province of the jury. This also left the jury, unfettered by possible bias and untimely distractions, to address the essential factual inquiry of whether the '737 patent claims read on the Versaport trocar, as well as the tangential question of whether the Green anticipation claims read on Surgical's Versaport trocar.

For these reasons, we cannot say that the trial court's exclusion of evidence that may be more prejudicial than probative was an abuse of its discretion. Nor can we say that Surgical's substantial rights were prejudiced by want of whatever support the administrative patent judge's opinion would contribute to Luther's testimony. Luther's credibility as an expert and the probative quality of his testimony come from his experience, presentation, and reasoning, and not those of the administrative patent

judge. There also is no evidence that this evidentiary ruling adversely affected the trial court's post-verdict enhancement of damages.

Finally, Surgical argues that the district court erred in excluding certain testimony from Luther about the scope of means-plus-function equivalents that the jury could consider in a direct infringement analysis. For example, in response to the question "And why did you find [the Green, Yoon, and Honkanen patents] helpful to your analysis on the question of equivalents?," Luther testified, "Well, if it's in the prior art, anything in the prior art, it's not available as an equivalent for purposes of considering infringement." This evidentiary ruling was not an abuse of the trial court's discretion, not only because Luther was being asked to testify beyond the scope of his expertise as a technical witness, but also because Luther's response to Surgical's questions can be relevant only under an erroneous construction of the law. *See, e.g., Intel Corp. v. United States Int'l Trade Comm.*, 946 F.2d 821, 842, 20 USPQ2d 1161, 1179 (Fed. Cir. 1991) ("It is not necessary to consider the prior art in applying section 112, paragraph 6. Even if the prior art discloses the same or an equivalent structure, the claim will not be limited in scope thereby. It is only necessary to determine what is an equivalent to the structure disclosed in the specification which is performing the function at issue.").

Conclusion

Accordingly, the judgment of the United States District Court for the Eastern District of Virginia is affirmed.

AFFIRMED

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

Civil Action 96-1217-A

APPLIED MEDICAL RESOURCES CORPORATION,
Plaintiff,

v.

U.S. SURGICAL CORPORATION,
Defendant.

REPORTER'S TRANSCRIPT

HEARING ON MOTIONS

Thursday, April 10, 1997

Before: THE HONORABLE T.S. ELLIS, III
Presiding

DISTRICT COURT RULING DENYING
SUMMARY JUDGMENT ON BEST MODE ISSUE

[98] RECAPITULATION BY THE COURT

THE COURT: Now we come to—I am going to take up briefly the best mode, which is a defense that is raised as to all three patents asserted by Applied.

Under 112, Paragraph 1, it's clear that the specification must contain a written description of the invention

and of the manner or process of making and using it, and shall set forth the best mode contemplated by the inventor of carrying out the invention.

There is a subjective part of it and an objective part, to the best mode analysis.

Invalidity on the best mode theory requires that the inventor know of a better mode of carrying out the invention than they disclosed, and that the inventors concealed the better mode.

[99] Now, compliance with the best mode requirement is typically a question of fact. And the failure to comply has to be proved or shown by clear and convincing evidence.

As I said, part of it is objective, part of it is subjective. The first part of it is wholly subjective, what the inventor knew at the time. The second inquiry is objective and looks at the adequacy of the disclosure.

In evaluating the adequacy of the disclosure, there are two objective limitations on the extent of the disclosure required.

First, it's whether a person with ordinary skill in the art would understand the best mode from the disclosure; and second, whether the scope of the claimed—the scope of the claim invention.

The scope of the invention must be defined in order for the Court to be able to conclude whether some process that might have been concealed constitutes a best mode of carrying out the invention.

In other words, you have to know what the invention is, because to put it in this context, for example, the question is whether the invention is a system of levers that predilates a septum seal is the invention, or whether the invention is something broader than that, [100] such that more than the friction necessary to break the septum so that the instrument can pass through is at issue, and

calls into issue the friction of moving the instrument about within the cannula, or cannula, is brought into play.

Another way to put it is: Unclaimed subject matter is not subject to the best mode disclosure requirements of Section 112. Otherwise, of course, the disclosure requirement would be boundless and, as the Engles case says, the pitfalls would be endless.

And illustrative of this is the rifle case, the Christiansen case, where an inventor of rifle parts who failed to disclose information allowing those parts to be interchangeable with all M-16 rifle parts resulted in invalidating the patents because the best mode of carrying out the claimed inventions did not involve—in other words, the invention did not involve making it interchangeable with the M-16 rifle. Interchangeableness was not part of the invention, and therefore failing to disclose the best mode of doing that was not fatal to that patent.

But it is true that unclaimed elements violate the best mode requirement, if such elements are necesary to practice the best mode of carrying out the claimed invention. [101] And we are not dealing again, to be clear, we are not dealing with the enablement requirement.

All of this deals with the Parylene-C, which is used to coat the septum seals in all three patents, in an effort to reduce the friction when the instruments are placed in the trocar and moved within the trocar.

None of the patents in the specs disclose Parylene-C as a mode of practicing the invention. It's not really contested, I think, that the use of Parylene-C to coat the seals would not be obvious to someone with ordinary skill in the art.

In fact, the record reflects that there was a lot of testing that took place to determine what seal coating would work out the best. So, if it's within the claimed invention, and if it is the best mode, and if he did know about it, then it would be an invalidating factor.

Applied contends that the use of Parylene-C is not critical to the claimed invention, because the claimed invention is not directed toward reducing the coefficient of friction between the instruments passing through the coated seals; and secondly, that Parylene-C is not the best mode because the seals coated with Parylene-C experienced problems with cracking, even after the patent application were filed.

[102] There is, in the Court's view, a remaining factual issue, at least, as to whether Parylene-C was believed by the inventor to be the best mode.

RULING BY THE COURT

THE COURT: Now, I have seen the books, the pages, that say this is it and all the rest of that; but I have also seen the testimony about the flaking that continued to occur on samples.

I can see that flaking could be a serious problem. It could—we are dealing with a matter that has to be sterile and clean, and I can see that would be a problem. So I am not going to decide the best mode issue at this time.

The parties may adduce whatever evidence they think is relevant to it. There is—and at the appropriate time I may hear more argument on it, but at this time I am not persuaded that any of the inventions are affected by what's called stiction, that is, the friction, the coefficient of friction, between the instrument and the septum valve material, which would be coated with the Parylene-C.

I have looked at the references in the specification and the claims of the patent, and it seems to me that the extent to which they are concerned with friction at all, they are concerned with the friction that [103] might increase the force required to insert an object through the septum.

That is not a friction that Parylene-C plays any role in ameliorating or relieving. I don't think Parylene-C makes it easier for a lever system to pre-expand the orifice and the septum.

I don't think Parylene-C creates greater protections for the seal or interacts better with the expandable leaf funnel system for creating greater seal protection, which is the second of the patents.

Nor do I think Parylene-C improves the trocar's capacity for off-axis manipulation of the instruments that are inside the cannula or within the trocar, without a reduction of the quality of the seal.

I am not deciding that finally now, but that's about where I am. But I do think there is a factual issue. So, that issue is delayed, that is, the factual issue with respect to what the inventor believed with respect to the use of Parylene-C as a coating on its septum seals.

Whether—I am familiar with the case that says it doesn't have to be the best of all possibles; it just has to be a better. But I can easily see that in this medical context, where the sterile nature of the area is of vital importance, that flaking could be a problem of [104] significant proportions.

So, the best mode matter is denied for now, but Surgical may renew this matter at the Rule 50 stage and I will consider it again at that time.

At that time—I think it's an important point, but at the moment I have told you what I consider to be the scope of the invention. But I am not going to hear further argument on it now. I have pretty well determined it is going to be done at the Rule 50 stage, not now.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

Civil Action No. 96-1217-A

APPLIED MEDICAL RESOURCES CORP.,
Plaintiff,

v.

UNITED STATES SURGICAL CORP.,
Defendant.

ORDER

The matter came before the Court on defendant's renewed motion for judgment as a matter of law, pursuant to Rule 50(b), Fed. R. Civ. P. The matter has been argued orally and in writing, and is now ripe for disposition.

For the reasons stated from the bench, defendant's renewed motion for judgment as a matter of law is DENIED.

The Clerk is directed to send copies of this Order to all counsel of record.

/s/ T.S. Ellis, III
T.S. ELLIS, III
United States District Judge

Alexandria, Virginia
May 9, 1997

RULING BY THE COURT
[May 9, 1997]

[27] THE COURT: Before the Court at the moment is the motion pursuant to Rule 50 for judgment as a matter of law on three grounds, that is, anticipation of the '553 by the Sure-Seal floating valve, anticipation of the '553 by the Endoport five millimeter trocar, and failure of Applied's inventors to disclose the best mode of [28] practicing the claimed invention.

Surgical points out that fewer than all three of the patents may be found invalid, and that it would not challenge the correctness of the damages awarded by the jury with respect to the remaining patent or patent found infringed.

These arguments were arguments that, of course, were asserted and vigorously pursued in the course of the trial.

Now, the—when I say the '553 Patent, I, of course, mean, I think it's Claims 1, 4 and 18; is that right? What were the claims?

ATTORNEY WALTER: Claims 4 and 18 are in issue, and Claim 1 is the independent claim.

THE COURT: Right. So, in effect, it was in issue, and that's really what was litigated, not other claims.

Now, judgment as a matter of law may be granted where there is only one reasonable conclusion as to the proper judgment. In other words, a reasonable fact finder, a jury, could not have reached any conclusion but the one asserted by the movant.

In determining whether the evidence presented at trial is sufficient to withstand a Rule 50 motion, the Court is not entitled to weigh the credibility [29] of the witnesses or to weigh the evidence. The evidence has to be viewed in the light most favorable to the non movant, in this instance Applied. It's a fairly stringent standard, and the

burden is on Surgical to show that there can only be one reasonable judgment.

Here, of course, the issue is—or the burden is particularly stringent because the questions on which Surgical bears the burden of proof at trial, here are questions where the burden was by clear and convincing evidence.

OrthoKinetics, in the Federal Circuit, said it in these terms:

> "A jury or a court may reach a conclusion that a patent remains valid solely on the failure of the patent challenger's evidence to convincingly establish the contrary. A patent is presumed valid at birth. Section 282. A patentee need submit no evidence in support of a conclusion of validity by a court or a jury.

In other words, even if Applied can point to no evidence or disputed fact, Surgical's evidence must still clearly and convincingly establish its invalidity defense as to be entitled to judgment as a matter of law under Rule 50.

* * * *

[35] Now we come to the best mode. I have heard considerable argument about the best mode. Prior to trial, the Court considered this at some length on summary judgment. Indeed, I think it was the second time it had been considered on summary judgment.

I thought about it long and hard, because there was very considerable amount of evidence about whether it was the best mode. However, I was concerned at the time as to whether it even needed to be disclosed, because it might not be necessary.

It didn't—it seemed to me that it may well not be necessary to the functioning of the invention that was claimed in the patent.

But ultimately, as the trial developed, there was a variety of testimony about it. Even if it was necessary

to the functioning of the invention—and there was testimony that it was not—there was a variety of [36] testimony on whether it was really preferred.

For example, Hart testified that while Gadberry loved Parylene-C, Hart himself liked silicone oil, and he said Ritchart probably liked something else, but he didn't know or he didn't say.

But ultimately, Ritchart chose Parylene-C and he says, not because it was necessary, is what Gadberry said.

Feinberg testified that it wasn't necessary to practice the invention, and there was also some amount of testimony that at the time of the application, there was still some difficulty with flaking.

And so, taken as a whole, a reasonable jury was not compelled to conclude that Surgical had proven a violation of the best mode requirement by clear and convincing evidence.

As I have indicated, there was plenty of evidence that it wasn't necessary to practice the invention. There was also evidence that it was not preferred at the time, and that they still had problems.

Now, there is the question embedded here as to whether the Court or the jury should determine whether the seals and the reduction of "stiction" was part of the claimed invention.

I think the jury made the same decision—[37] it appears that the jury made precisely the same decision that the Court would make, if it is a question of law, and that is that it isn't necessary to practice the invention.

But quite apart from that, they could have made it on the alternate ground that it wasn't clear and convincing that it was the best mode. There might have been other problems and other preferences.

So, the motion for Rule 50 judgment as a matter of law post verdict is denied.

* * * *

APPENDIX D

[Filed Aug. 21, 1998]

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

APPLIED MEDICAL RESOURCES CORPORATION,
Plaintiff/Appellee,

v.

UNITED STATES SURGICAL CORPORATION,
Defendant-Appellant.

ORDER

A combined petition for rehearing and suggestion for rehearing in banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the APPELLEE, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on August 28, 1998.

For the Court,

/s/ Jan Horbaly
JAN HORBALY
Clerk

Dated: August 21, 1998

60 6/17/91 Don G

Rec'd Parylene-C coated septums — C-Flex material from Vikem Technology

Process # 1 — LOOKS ACCEPTABLE!

This process involved a low gas flow rate together with a low power level for plasma etching prior to coating.

The septum portion (adjacent the orifice) was stretched beyond the "in use" range with no noticeable separation of the coating from the substrate material.

The diaphragm portion (bordering the center hub) was stretched far beyond reason, resulting in a separation off the coating and initiating peeling from the substrate material. In use the diaphragm will not be subjected to the stretching performed in this initial testing. It should not separate each peel. This, however, must be demonstrated in the future with the revision D or E septums, which will not pop off of the lever mechanism as did these sample rev. C septums used.

The friction coefficient is acceptably low enough to permit any sized probe to pass thru without the stiction experienced on uncoated parts. In other words — it looks great!

Process #2 — Failed miserably — the coating separated easily from the C-Flex. This was done with a high gas flow + high power plasma etch.

APPENDIX F

UNITED STATES PATENT

Ritchart et al.

Patent Number: 5,209,737
Date of Patent: May 11, 1993

LEVER ACTUATED SEPTUM SEAL

Inventors:

Mark A. Ritchart, Murrieta;
Robert F. Cooper, Yorba Linda;
Charles C. Hart; Donald L. Gadberry, both of Huntington Beach, all of Calif.

Assignee:

Applied Medical Resources, Inc.,
Laguna Hills, Calif.

Appl. No.: 732,141

Filed: Jul. 18, 1991

Int. Cl.[5] A61M 5/178
U.S. Cl. 604/167; 604/256
Field of Search 604/167, 169, 160, 161, 604/256, 164, 236, 200, 201, 202, 205, 264, 165, 166, 905; 251/149.1; 137/843, 844, 845, 849

References Cited

U.S. PATENT DOCUMENTS

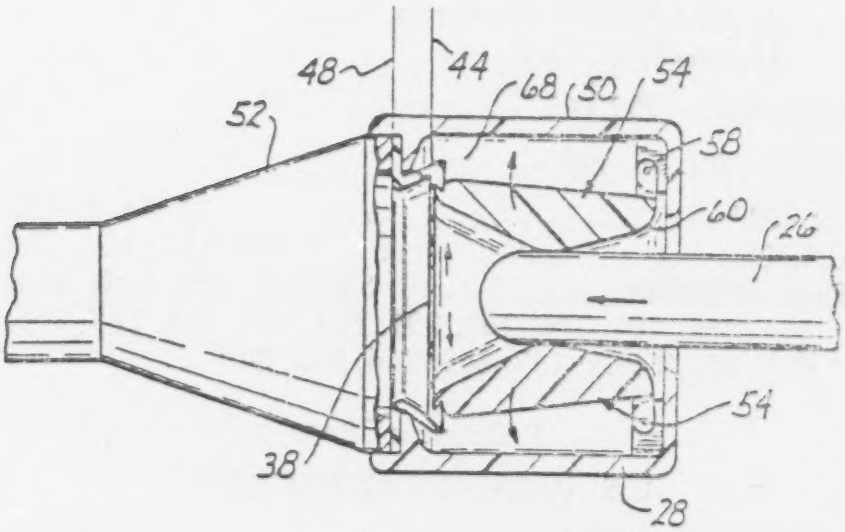
4,723,550	2/1988	Bales et al.	604/256
4,842,591	6/1989	Luther	604/167

Primary Examiner—Cary E. O'Connor
Attorney, Agent, or Firm—Richard L. Myers

ABSTRACT

A septum valve in a trocar asembly has a variable orifice that is responsive to a cross-sectional dimension of the surgical instrument being inserted into the trocar channel, thereby minimizing leakage of inflation gas from the body cavity, such as the abdomen, being operated on. An elastomeric septum is disposed in the channel and includes portions which define an orifice having in a relaxed state a first cross-sectional area. An actuation assembly provided with levers which pivot radially outwardly to expand the seal and thereby expand the orifice to the second cross-sectional area in response to entry of the instrument into the channel. The actuation assembly is free to float in an annular recess to accommodate an instrument which is misaligned with the trocar channel.

32 Claims, 4 Drawing Sheets



'737 ASSERTED CLAIMS 1 AND 32

ASSERTED CLAIM 1

1. A trocar assembly having a channel defined along an elongate axis, the trocar assembly being adapted to receive an instrument having a particular cross-sectional dimension, said trocar assembly comprising:

an elastomeric septum disposed in said channel and including portions defining an orifice having in a relaxed state a first cross-sectional area and in an expanded state a second cross-sectional area; and

means responsive to the particular dimension of the instrument for expanding said orifice to the second cross-sectional area.

ASSERTED CLAIM 32
(which includes claims 30 & 29)

32. The assembly recited in claim 30 wherein the moving means includes a plurality of levers each pivotal on the frame and positioned to engage the object and to move the hole portions of the septum a distance proportional to the size of the object.

30. The assembly recited in claim 29 wherein the actuation means includes a frame and means pivotal on the frame for moving the septum portions to enlarge the hole.

29. A seal assembly adapted to receive an elongate object and to form a seal around the object, the assembly comprising:

a housing including first portions defining a channel extending through the housing, and second portions defining a peripheral recess in the housing;

a septum extending across the channel of the housing;

portions of the septum defining a hole adapted to receive the object with the septum portions forming a seal around the object;

the septum portions engaging the object through the channel;

actuation means movable within the peripheral recess of the housing for enlarging the hole in response to insertion of the object into the channel; whereby

the friction forces are reduced to facilitate further movement of the object through the channel of the housing.

APPENDIX G

UNITED STATES PATENT

Hart et al.

Patent Number: 5,308,336
Date of Patent: May 3, 1994

SEAL PROTECTION MECHANISM

Inventors:

Charles C. Hart, Huntington Beach;
Mark A. Ritchart, Murrieta, both of Calif.

Assignee:

Applied Medical Resources,
Laguna Hills, Calif.

Appl. No.: 952300
Filed: Sep. 28, 1992

Related U.S. Application Data

Continuation-in-part of Ser. No. 732,141, Jul. 18, 1992, Pat. No. 5,209,737.

Int. Cl.[5] A61M 5/178
U.S. Cl. 604/167; 604/256
Field of Search 604/167, 256

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4,240,211	12/1980	Hosono	604/167

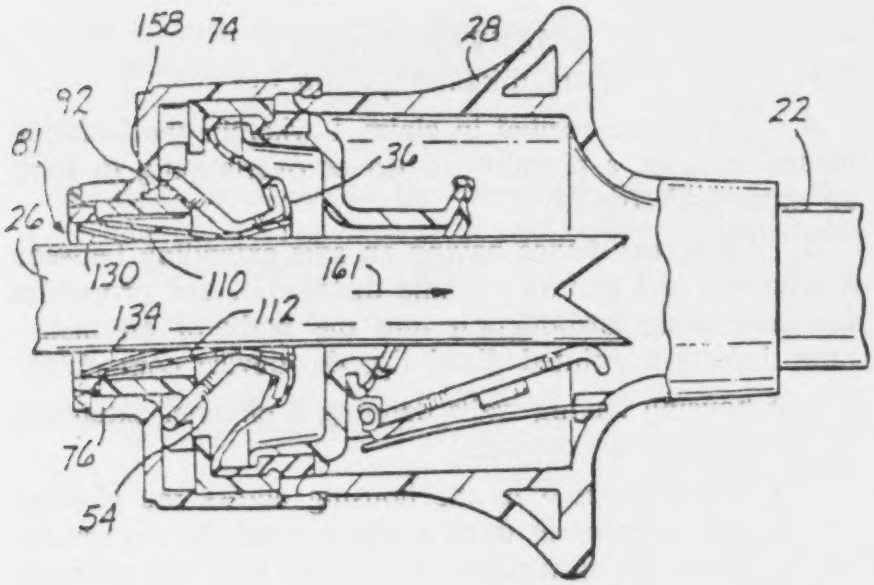
4.430,081	2/1984	Timmermans	
4.673,393	6/1987	Suzuki	
4,715,360	12/1987	Akui et al.	604/256
4,723,550	2/1988	Bales	
4,758,225	7/1988	Cox et al.	604/167
4,842,591	6/1989	Luther	
4,857,062	8/1989	Russell	
4,909,798	3/1990	Fleischhacker	
4,929,235	5/1990	Merry et al.	604/167
4,960,412	10/1990	Fink	
4,966,588	10/1990	Rayman	
5,104,383	4/1992	Schichman	604/167
5,127,626	7/1992	Hilal et al.	604/167
5,156,596	10/1992	Balbierz et al.	604/167
5,180,373	1/1993	Green et al.	604/167
5,197,955	3/1993	Stephens et al.	604/167

Primary Examiner—Paul J. Hirsch
Attorney, Agent, or Firm—Richard L. Myers

ABSTRACT

An access device has an axis extending between a proximal end and an opposing distal end, and properties for facilitating introduction into the body of an instrument having a pointed distal tip. The device includes a housing having walls defining a channel extending through the device and a valve disposed in the housing across the channel and adapted to form a seal around the instrument. The valve includes inner portions defining an aperture to receive the instrument and outer portions extending radially outwardly of the inner portions. Means carried by the housing is positioned to be disposed between the instrument and at least the outer portion of the seal for isolating the seal from the pointed distal tip during insertion of the instrument.

24 Claims, 5 Drawing Sheets



'336 ASSERTED CLAIMS 4 AND 23

ASSERTED CLAIM 4
(which includes claim 1)

4. The device recited in claim 1 wherein the isolation means includes a plurality of leaves overlapping to form an expandable funnel.

1. An access device having an axis extending between a proximal end and an opening distal end, and properties for facilitating introduction into the body of an instrument having a pointed distal tip, the device comprising:

a housing having walls defining a channel extending through the device;

a valve disposed in the housing across the channel and adapted to form a seal around the instrument when the instrument is inserted into the channel;

the valve including inner portions defining an aperture to receive the instrument and outer portions extending radially outwardly of the inner portions;

means having a continuous, generally conical inner surface engageable by the instrument, and positioned between the instrument and at least the outer portion of the valve for isolating the valve from the pointed distal tip during insertion of the instrument;

the valve being formed of an elastomeric material; and

the isolating means being formed of a material having compliance less than that if the elastomeric material forming the valve in order to distribute the insertion forces along the valve.

ASSERTED CLAIM 23

23. A trocar assembly having a channel defined along an elongate axis and adapted to receive an instrument

having a particular cross-sectional dimension and a sharp distal tip, the trocar assembly comprising:

an elastomeric septum disposed in said channel and including portions defining an orifice having in a relaxed state a first cross-section area and in an expanded state a second cross-sectional area;

means responsive to the particular dimension of the instrument for expanding said orifice to the second cross-sectional area; and

means having a continuous, generally conical inner surface engageable by the instrument and positioned between the instrument and the septum for isolating the septum from the sharp distal tip of the instrument during insertion of the instrument.

APPENDIX H

UNITED STATES PATENT

Hart et al.

Patent Number: 5,385,553
Date of Patent: Jan. 31, 1995

TROCAR WITH FLOATING SEPTUM SEAL

Inventors:

Charles C. Hart, Huntington Beach;
Mark A. Ritchart, Murrietta;
Donald L. Gadberry, San Juan Capistrano,
all of Calif.

Assignee:

Applied Medical Resources Corporation,
Laguna Hills, Calif.

Appl. No.: 77,005

Filed: Jun. 15, 1993

Related U.S. Application Data

Continuation-in-part of Ser. No. 952,300, Sep. 28, 1992, Pat. No. 4,308,336, which is a continuation-in-part of Ser. No. 732,141, Jul. 18, 1991, Pat. No. 5,209,737.

Int. Cl.[6] A61M 39/04
U.S. Cl. 604/167; 604/256
Field of Search 604/167, 256

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4,673,393	6/1987	Suzuki	
4,715,360	12/1987	Akui et al.	
4,723,550	2/1988	Bales	
4,758,225	7/1988	Cox et al.	604/126
4,842,591	6/1989	Luther	604/167
4,857,062	8/1989	Russell	
4,909,798	3/1990	Fleischhacker	
4,917,668	4/1990	Haindl	604/167
4,929,235	5/1990	Merry et al.	604/167
4,960,412	10/1990	Fink	604/167
4,966,588	10/1990	Rayman	
5,104,383	4/1992	Schickman	
5,127,626	7/1992	Hilal et al.	604/167
5,180,373	1/1993	Green et al.	604/167
5,197,955	3/1993	Stephens et al.	604/167
5,209,737	5/1993	Ritchart et al.	604/256

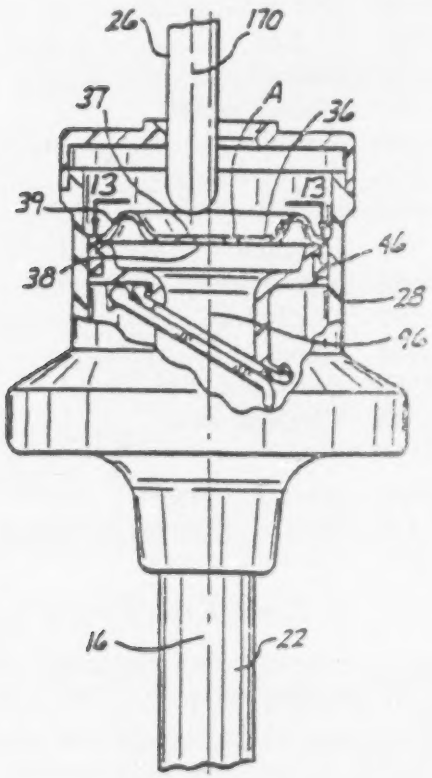
Primary Examiner—Paul J. Hirsch
Attorney, Agent, or Firm—Richard L. Myers

ABSTRACT

A trocar having a cannula and housing which define an access channel, is configured to receive a surgical instrument. A flexible valve disposed in the channel includes first portions which define an orifice through the valve and second portions which are disposed outwardly of the first portions. The second portions are provided with a greater flexibility so that when the instrument is inserted off-axis, the second portions of the valve will deform before the first portions causing the orifice to move without substantial deformation to the off-axis location. Al-

ternatively, levers engaging the first portions of the valve can be pivotally mounted on a floating ring to move the substantially undeformed orifice to the off-axis location. An associated method includes the steps of deforming the second portions of the valve without substantially deforming first portions of the valve to move the orifice into axial alignment with the instrument.

25 Claims, 6 Drawing Sheets



'553 ASSERTED CLAIMS 4 AND 18

ASSERTED CLAIM 4
(which includes claims 3 & 1)

4. The trocar recited in claim 3 wherein the second portions of the valve have a bellows configuration.

3. The trocar recited in claim 1 wherein the first portions of the valve have a first radial length to radial distance ratio;

the second portions of the valve have a second radial length to radial distance ratio; and

the second ratio is greater than the first ratio.

1. A trocar adapted to form an access channel across a body wall, and configured to receive a surgical instrument, the trocar comprising:

a cannula having an axis extending between a proximal end and a distal end of the trocar;

a seal housing disposed at the distal end of the cannula and forming with the cannula the access channel of the trocar;

a flexible valve disposed relative to the housing and across the access channel, the valve having elastomeric properties for forming a seal with the instrument when the instrument is disposed in the access channel;

first portions of the valve defining an orifice which is normally concentric with the axis of the cannula, the first portions being sized and configured to receive the instrument and form the seal with an outer surface of the instrument; and

second portions of the valve disposed circumferentially outwardly of the first portions of the valve for facilitating movement of the orifice from a first

position generally concentric with the axis of the cannula to a second position generally removed from the axis of the cannula, in response to insertion of the instrument along a line removed from the axis of the cannula.

ASSERTED CLAIM 18

18. An access device adapted to form an access channel across a body wall, and configured to receive a surgical instrument in the access channel, the access device comprising:

a cannula having an axis extending between a proximal end and a distal end of the device;

a seal housing disposed at the distal end of the cannula and forming with the cannula the access channel of the device;

a flexible valve disposed relative to the housing and across the access channel, the valve having elastomeric properties for forming a seal with the instrument when the instrument is disposed in the access channel;

portions of the valve defining an orifice which is sized and configured to receive the instrument and to form the seal with an outer surface of the instrument; and

means disposed circumferentially outwardly of the valve portions for supporting the valve portions within the seal housing, the supporting means being movable relative to the housing to permit the valve portions to float relative to the axis of the cannula.

APPENDIX I

Excerpts, Testimony of Inventor Mark A. Ritchart
(April 23, 1997)

DIRECT EXAMINATION BY U.S. SURGICAL

* * * *

[174] Q. Did you experiment with coating?

A. Yes, we did.

Q. Over what period of time?

A. I don't remember exactly what period of time. We experimented for a while.

Q. Did you ultimately decide on a coating?

A. We did.

Q. What did you decide on?

A. We decided on the Parylene-C coating.

Q. Who came up with Parylene-C?

A. It was an idea by Don Gadberry, I believe.

Q. Had it ever been used on any of your seals before that time?

A. No.

Q. Did you test Parylene-C?

A. Yes, we did.

Q. What was the nature of the testing of Parylene-C?

[175] A. It was, as I had indicated earlier, we would coat the seals with Parylene and pass instruments through, and we would see if that made a difference:

Did it make it easier?

Was the seal less susceptible to tearing?

Did the Parylene adhere very well to the C-flex material?

Q. Did you ultimately decide to use Parylene-C?

A. Yes, we did.

Q. Why?

A. It seemed to give us an advantage. It did reduce the frictional force. It did protect the seal a little bit better than ones that hadn't been coated.

Q. At the time the patent application was filed in July of 1991, did you have a preferred coating?

A. Yes.

Q. And what was that?

A. That was the Parylene.

Q. And why was that?

A. It was the best coating material that we could come up with.

Q. Now, both the '336 and '553 patents include a seal, do they not?

A. Yes.

Q. And the '737?

[176] A. Yes.

Q. With respect to all three of your inventions, could these inventions work without Parylene-C?

ATTORNEY NEAL: Objection, another expert opinion.

ATTORNEY KURZWEIL: It is not an expert opinion.

THE COURT: You said "did they work?"

ATTORNEY KURZWEIL: "Could they."

THE COURT: I'll overrule it.

You may answer.

THE WITNESS: No, they didn't.

BY ATTORNEY KURZWEIL:

Q. Why didn't they work?

A. The seal was way too sticky and susceptible without some sort of coating on it.

(Pause)

THE COURT: Do you have anything further?

ATTORNEY KURZWEIL: Yes.

THE COURT: —How much further?

ATTORNEY KURZWEIL: Ten minutes maybe, less.

THE COURT: All right, proceed.

BY ATTORNEY KURZWEIL:

Q. Was the product eventually test marketed with Parylene-C?

[177] A. Yes.

Q. Were all the prototypes tested with Parylene-C?

A. Yes.

Q. Was there another coating you preferred over Parylene-C?

A. No.

CROSS EXAMINATION BY APPLIED

* * * *

[206] Q. You would agree that the invention in the '737 Patent is the use of levers to predilate the septum seal correct?

A. That's correct.

Q. And you would agree that when levers are used to predilate the septum seal, Parylene coating is not involved in that function; would you agree with that?

A. It's not involved in the actual work associated [207] with dilating the septum, no.

Q. Okay. And the purpose of the '336 Patent was to have a physical protection for the septum seal, correct?

A. Yes.

Q. And that was what was, as you understood it, the coverage of the '336, core of the 336?

A. The physical protection mechanism, yes.

Q. And Parylene-C was not part of that physical protective mechanism in the '336, correct?

A. In our product it was. In the '336, it was not.

Q. And the '553, the novel item in that invention was one of—had to do with the aspect of floating; is that correct?

A. Yes.

Q. And had to do with particular aspects of floating, correct?

A. Yes.

Q. And the particular aspects of floating that were covered by the '553 were not impacted by Parylene-C, correct?

A. Well, again, that's not shown in the patent. I think we called that an oversight. But it was one of the components that made up our seal.

Q. Well, but the stopcock valve was also one of the components, correct?

[208] A. Correct.

Q. What I am saying, if you focus on what the invention, the invention covered by the '553 had to do with the ability of the seal to move laterally with an instrument in it, correct?

A. The—

ATTORNEY NEAL: Objection.

THE COURT: Just a moment.

Yes, Mr. Kurzweil?

ATTORNEY KURZWEIL: I believe there was a mischaracterization in reference to the seal, a stopcock being part of the seal. I object to the form of the question.

THE COURT: All right, it's overruled. The witness can correct anything in the predicate of the question that is incorrect.

You may reask your question and correct it, if you agree. Otherwise, leave it as it is and the witness may answer.

ATTORNEY NEAL: I think—let me just ask you a totality different question.

BY ATTORNEY NEAL:

Q. In the action of moving the septum seal back and forth, laterally with an instrument in it—are you with me as to what I am asking about?

[209] A. I think so.

Q. (Continuing)—the Parylene-C is not implicated in that side-to-side movement of the seal structure, is it?

A. No, it's not.

REDIRECT EXAMINATION BY U.S. SURGICAL

* * * *

[218] Q. You were asked some questions about what went into the patent. Do you know who actually prepared the patent on—or patents, for all three of the patents?

A. Yes.

Q. Who prepared them?

[219] A. Dick Meyers.

Q. And who was Mr. Meyers?

A. He is patent counsel for Applied.

Q. And is it your the testimony that you simply forgot to tell Mr. Meyers about Parylene-C?

A. Yes.

Q. Now, Mr. Neal asked you some questions—

THE COURT: You have to avoid leading.

ATTORNEY KURZWEIL: I understand, your Honor.

BY ATTORNEY KURZWEIL:

Q. Mr. Neal asked you some more questions about Parylene and the possibility of flaking. Do you recall those questions?

A. Yes.

Q. As of the time the '737 prototype was released, did you regard Parylene-C as the best coating material available for that device?

A. Yes, I did.

Q. And in the absence of Parylene-C, did you regard the device as capable of working?

A. No.

Q. And with respect to the cone protector, was Parylene-C also necessary?

A. Yes, it was.

[220] Q. And with respect to the '556, the floating seal, '553, the floating seal, would your answer be the same for that?

A. Yes, it would be.

* * * *

APPENDIX J

Excerpt, Testimony (By Deposition) of
Inventor Donald L. Gadberry
(April 23, 1997)

DIRECT EXAMINATION BY U.S. SURGICAL

* * * *

[209] Q. Turn to page 52171,* please.

Now, on this page you are discussing the Parylene-C coated septums, correct?

A. Yes.

Q. And the septums that you are talking about are made of C-flex material coated with Parylene-C?

A. Yes.

Q. And you're indicating on this page that a process that involves a low gas flow, together with a low power level for plasma etching, prior to coating of the septum with Parylene-C, is a process that yields good results?

A. Yes.

Q. And by the notation on the left-hand column, 'This is it,' you are indicating that you were satisfied that process number one was acceptable?

A. Yes.

Q. And provided good results?

A. I would have to read it to see what the results were. So far, our development looks like this might be a good coating although it [210] needed to be tested further, too.

Q. Indeed, your observation in this passage on this page was that the friction achieved with the Parylene-C coated C-flex septum was acceptably low enough to permit any size trocar to pass through without the stiction experienced on uncoated parts, correct?

A. That's correct.

---

* Document 52171 is the June 17, 1991 entry from inventor Galbury's Laboratory Notebook at A. 24a, *supra*.

Q. And by 'stiction,' you mean a reduction—by 'stiction,' you are referring to friction, correct?

A. Right. Particularly at this time we were using the very, very low durometer C-flex, the five durometer, which is the next thing closest to syrup.

Q. Your conclusion was that it looks great?

A. Yes.

Q. You wrote that document—you made that entry into your notebook on or about June 17th, 1991?

A. Yes.

Q. And everything that's written on page 52171 was written on June 17th, 1991?

A. Yes.

APPENDIX K

Excerpts, Testimony of Inventor Charles C. Hart
(April 15, 1997)

CROSS-EXAMINATION BY U.S. SURGICAL

* * * *

[43] Q. And that confirmed your expectation, did it not, that in this uncoated form those low durometer C-flexes were very sticky?

A. They were very sticky to handle.

Q. They would stick to an instrument if it were pushed through, in an uncoated fashion?

A. If you tried to push it through without stretching open the septum or something, if you just tried to push an instrument through it, it was somewhat sticky, yes.

Q. And so you set about—or you and others at Applied set about finding the optimum coating material to [44] apply to that seal, correct?

A. At least one of the members of our group had that assignment, yes, or took it upon himself to do that, yes, sir.

Q. Well, you reported at this time—and by "this time" I mean 1991—to Mark Ritchart, did you not, within Applied?

A. Yes, I did.

Q. And so did Mr. Don Gadberry also report to Mr. Ritchart?

A. Yes, sir.

Q. And am I also correct, that Mr. Gadberry had sort of the primary responsibility for searching out and locating the proper coating material for use on these C-flex seals?

A. That's possible. I am not aware that he had that assignment. But he was very capable of discovering things like that, yes, sir.

Q. And as a result of that search effort, I am correct, am I not, the a substance by the name of Parylene-C was selected as the preferred coating for the C-flex seals?

A. It was selected as a surface treatment and coating, yes, sir. But I would hesitate to say "preferred."

[45] Q. Well, did Applied ever conclude in 1991 that there was a better coating material than Parylene-C?

A. Are you talking about Applied as an entity, or Applied—

Q. I am talking about did you or anyone, to your knowledge, within your R&D group ever conclude that there was a better coating material for use with Applied's C-flex seals, other than Parylene-C?

A. Well, I did, yes, sir.

Q What about Mr. Gadberry?

A. Well, Mr. Gadberry was in love with Parylene because he found it, and I liked silicon oil, and Mark Ritchart probably liked something else. We had our opinions on that.

Q. But the material that was selected and used was Parylene-C, nevertheless, that's correct—is that correct?

ATTORNEY NEAL: Object to the form; used for what?

THE COURT: Overruled.

You may answer.

THE WITNESS: Well, Mark was the boss, and so he got his way with using Parylene on at least, at least some of the seals. He got his way most of the time, but not all of the time.

[46] BY ATTORNEY WALTER:

Q. And in addition to finding Parylene-C, it was also necessary to find a particular way to coat that Parylene-C onto the seal, correct?

A. I believe so.

Q. Do you recall that there was some effort and experimentation involved in determining the best way in

which to actually apply that Parylene-C coating to the seals?

A. Yes. The Parylene-C sort of took on a life of its own. In our engineering group, things have a tendency to turn into little challenges and projects along the way. Whether we were going to use Parylene-C on the seal became somewhat immaterial.

The Holy Grail turned into something else. It was: How in the world can you put something like this on a soft seal?

Parylene-C is a plastic. It's not really an elastomeric or rubber-like material. And so we thought it's a really interesting challenge to try to put this kind of a coating on an elastic seal that's going to stretch maybe 800 percent, and make it stay there.

And so our group looked at that, even though we are not in the business of putting surface coatings on or anything like that.

[47] The individual that was doing it was a rather innovative and creative guy, and he kept interfacing with us and we kept interfacing with him, and it turned into just an interesting project of its own, even though in my opinion it was not the best material to use.

Q. Well, my question to you, sir, was: Isn't it a fact that a fair amount of experimentation took place in order to determine a way in which to apply this Parylene-C to your C-flex seals?

A. Yes, sir. It was a fascinating experiment.

* * * *

REDIRECT EXAMINATION BY APPLIED

* * * *

[72] Q. You were asked a series of questions about Parylene-C. Do you recall those questions?

A. Yes, sir.

Q. Does Parylene-C in any way affect the degree to which the levers in the '737 Patent can open the septum seal?

[73] A. No.

Q. Does Parylene-C in any way impact the isolation or seal protection means described in the '336?

A. No, not in any way.

Q. Does Parylene-C in any way impact the ability of a seal to float, as depicted in '737 or '553?

A. No, sir.

Q. You said that you didn't like Parylene-C. Why is that?

A. Well, it's not that I didn't like it. It just wasn't—it was foreign thing, and standard medical lubrications are for something else. And Parylene was good for what it was for, what it was designed for, and the standard lubricants were better, in my estimation, for what they were normally used for.

* * * *

APPENDIX L

Excerpt, Testimony of Applied Expert Witness
Barry Feinberg (April 24, 1997)

DIRECT EXAMINATION BY APPLIED

* * * *

[216] Q. Do you have an opinion as to whether a lubricant [217] is necessary to practice the invention that is disclosed in the '737 Patent?

A. Yes, I do.

Q. And what is your opinion in that regard?

A. That it is not necessary.

Q. And what is the basis of that opinion?

ATTORNEY WALTER: Objection. I object to this line of questioning, your Honor. There is no foundation for this witness to know what would be necessary to practice these inventions.

THE COURT: Overruled. You may cross-examine.

BY ATTORNEY NEAL:

Q. What is the basis of your conclusion?

A. The full understanding of the function and operation of the device, and also looking at the patent.

Q. And what is your understanding of the function of—of the device as it relates to the question of whether a lubricant is necessary to practice it?

A. Well, the key issue has been talking about friction and friction forces, and the patent limits itself to the friction force due to the instrument passing through the septum. And that friction force is due to the normal force or the compressive force of that septum seal on the instrument coming through.

[218] And the reduction of friction, which is talked about in the patent, deals with the lever system predilating that diaphragm and, therefore, limiting the amount of closure, in a sense, that the septum seal can have. And

therefore, that's a mechanism for reducing friction, and that mechanism is independent of lubrication.

Q. Does lubrication have anything to do with the operation of that lever system?

A. No.

Q. Do you have an opinion as to whether a lubricant is necessary for the practice of the invention in the '336 Patent?

A. No, it is not.

Q. What is the basis of that opinion?

A. Same as before.

Q. Do you have an opinion as to whether a lubricant is necessary to practice the invention in the '553 Patent?

A. Yes.

Q. And what is the basis of that?

A. Same analysis applies.

Q. Would you—

THE COURT: What is the opinion? You said you had one.

THE WITNESS: I'm sorry. The lubricant is [219] not necessary.

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No. 98-779

IN THE

Supreme Court of the United States

OCTOBER TERM, 1998

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Petitioner,

v.

APPLIED MEDICAL RESOURCES CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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RESPONDENT'S BRIEF IN OPPOSITION

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STATEMENT PURSUANT TO RULE 29.6

Respondent Applied Medical Resources Corporation is not a publicly traded company and has no parent company, subsidiaries, or affiliates that have issued shares to the public.

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RESPONDENT'S BRIEF IN OPPOSITION

INTRODUCTION

United States Surgical Corporation's petition identifies no legitimate basis for this Court to review the Federal Circuit's unanimous decision to uphold the jury's verdict in this case. In a fruitless effort to manufacture an issue meriting this Court's review, the petition misapplies controlling precedent and seriously distorts the panel's decision and the record evidence.

Contrary to petitioner's argument, the panel applied well-settled law in addressing—and rejecting—petitioner's

contention that the patent claims at issue are invalid because the patents did not disclose the inventors' "best mode" for carrying out the claimed inventions. Consistent with this Court's decision in *Aro Manufacturing Co. v. Convertible Top Replacement Co.*,[1] the panel first construed the claims *as a whole* to determine the scope of the claimed inventions, and did not limit its analysis to a single claim element. Then, the panel reviewed the trial evidence and concluded that there was not clear and convincing evidence that Parylene-C—the alleged "best mode" —was part of carrying out the claimed inventions. As such, the panel properly ruled that petitioner had not met its heavy burden of establishing one of the two essential components of a best mode violation.[2] This is hornbook best mode law and presents no issue warranting this Court's review.

In its request that the Federal Circuit review the challenged panel decision *in banc*, petitioner made the same argument it is advancing here—and relied on the same misrepresentations of the record and the panel's opinion. Not surprisingly, not a single Federal Circuit Judge dissented from that court's determination that *nothing* about this case warranted *in banc* review of the panel's unanimous decision upholding the jury's verdict. The reason is simple: the purported "inconsistency" between the panel's

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[1] 365 U.S. 336, 344 (1961).

[2] To prevail in its claim that the patent claims at isssue are invalid becaue the patents did not disclose Parylene-C as a lubricant, Surgical was required to prove by clear and convincing evidence *both* (1) that Parylene-C (a lubricant coating) was involved in carrying out the claimed inventions; *and* (2) that Parylene-C was the inventors' preferred lubricant at the time the patent applications were filed. *See* 35 U.S.C. § 112 ¶ 1. The district court found that *neither* had been established by clear and convincing evidence. *See* Petition Appendix ("Pet. App.") 21a-22a. Because the panel found that Surgical had failed to prove that Parylene-C was part of carrying out the claimed inventions (Pet. App. at 5a), it did not address whether Parylene-C was the inventors' preferred coating at the time the patent applications were filed.

decision and "years of decisions" applying the best mode requirement of 35 U.S.C. § 112 ¶ 1 is illusory. Stripped of its bluster and misstatements, the petition reduces to a complaint that every decision maker that has considered petitioner's argument for invalidating respondent's patents —the jury, the district court, the panel, and the Federal Circuit as a whole—has rejected it. Petitioner's dissatisfaction with that result is not a basis for certiorari.

THE PETITION MISSTATES THE RECORD AND THE PANEL'S DECISION

The petition contains several significant misstatements about the trial record and proceedings below.

Petitioner asserts erroneously that there was *undisputed* evidence that Parylene-C was the inventors' preferred coating.[3] In fact, the evidence was, at best, conflicting on this point. On cross-examination by petitioner, co-inventor Charles Hart testified that Parylene-C was *not* his preferred coating for the septum seal and that he preferred silicon oil.[4] Likewise, contrary to petitioner's suggestion, co-inventor Donald Gadberry's testimony was that *he did not know why* Applied chose Parylene-C instead of other coatings.[5]

Indeed, even co-inventor Mark Ritchart, a hostile *former* employee called by petitioner, reluctantly conceded on cross-examination that, at least as late as eight months *after* the '737 application was filed, Parylene-C was still flaking, which posed a contamination problem if flakes fell into the patient, and therefore still was not working as an acceptable (let alone *preferred*) seal coating.[6]

Petitioner also states erroneously that the panel "acknowledged" that Parlyene-C was the inventors' preferred

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[3] Pet. at 6.

[4] Pet. App. at 47a.

[5] Opposition Appendix ("Opp. App.") (attached hereto) at 1a-2a.

[6] Opp. App. at 3a-5a.

seal lubricant.[7] Petitioner reads too much into the panel's statement that "Surgical concludes that the patents are invalid for failing to disclose the use of Parylene-C—which *at some point* became the preferred lubricant for coating the seal . . . ." [8] The panel *did not discuss* the evidence relating to whether the inventors preferred Parylene-C at the time the patent applications were filed—the relevant point in time for purposes of a "best mode" analysis. Although the district court specifically found that "[t]here was . . . evidence that [Parylene-C] was not preferred at the time," [9] the panel did not have to reach this *additional* issue, because it concluded that the jury's verdict was sustainable based on the lack of clear and convincing evidence that Parylene-C was involved in *carrying out* the claimed inventions. The portion of the panel's decision on which petitioner relies seems to be the panel's summary recapitulation of petitioner's argument; it is plainly not a rejection of the district court's determination that there was no clear and convincing evidence that Parylene-C was the inventors' preferred coating at the time the patent applications were filed.[10]

Petitioner likewise repeatedly asserts—without accounting for the contrary testimony—that the evidence established that Parylene-C "was necessary to carry out the

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[7] Pet. at 7.

[8] Pet. App. at 4a-5a (emphasis supplied).

[9] Pet. App. at 22a.

[10] Petitioner also suggests erroneously that the Federal Circuit has decided that the failure to disclose a single co-inventor's preferred "mode" for carrying out an invention is a basis for invalidation under 35 U.S.C. § 112 ¶ 1 even if other co-inventors prefer a different "mode." Pet. at 3, n.3. The footnote from *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351, n.5 (Fed. Cir. 1998), on which petitioner relies is, at best, ambiguous dictum and plainly not a holding that where, as here, there is *affirmative disagreement* among the co-inventors, the inventive entity has a "preferred mode."

inventions." [11] In fact, there was substantial trial testimony from co-inventors Hart and Ritchart as well as respondent's expert, Dr. Feinberg, that Parylene-C had nothing to do with carrying out the claimed inventions.[12] After recounting that testimony, the district court stated bluntly that "there was plenty of evidence that [Parylene-C] wasn't necessary to practice the invention."[13] The panel, having reviewed the same testimony, agreed.[14]

Petitioner also mischaracterizes respondent's arguments in the trial court and the Federal Circuit.[15] Respondent did not argue that the courts should ignore *any* claim element in construing the claims in suit. Rather, respondent argued that the court should construe the claims as a whole to determine their proper scope and meaning—and thus identify "the invention" of each patent for purposes of § 112 ¶ 1.[16] Respondent also argued there was no clear and convincing evidence that Parylene-C was related to carrying out the inventions of the three patents or that Parylene-C was the inventors' preferred coating at the time any of the patent applications were filed. Applying set-

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[11] Pet. at 3.

[12] Pet. App. at 48a-49a; 41a-42a; 50a-51a. Petitioner also asserts erroneously that the seals themselves will not work without Parylene-C. Pet. at 3, 5, 6, 7, 10. In fact, the evidence established that the seals could be coated with other lubricants, e.g., silicon oil, and that such lubricants were common in dealing with trocars. Opp. App. at 6a; Pet. App. at 47a.

[13] Pet. App. at 22a.

[14] Pet. App. at 5a.

[15] Pet. at 6-7.

[16] *Chemcast Corp. v. Arco Industries Corp.*, 913 F.2d 923, 927, 16 U.S.P.Q.2d 1033, 1036 (Fed. Cir. 1990) (" 'The focus of the best mode requirement, as it was with the enablement requirement, is on the *claimed* invention. Thus, before determining whether there is evidence of concealment, the scope of the invention must be delimited.' ") (quoting *Christianson v. Colt Indus. Oper. Corp.*, 870 F.2d 1292, 1301 (7th Cir. 1989) (emphasis in original)).